Cohere Medical Policy -
Cardiac Contractility Modulation (CCM)

Clinical Policy for Medical Necessity Review

Version: 2
Cohere Health UMC Approval Date: August 14, 2025
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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medical Policy - Cardiac Contractility Modulation (CCM)

Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Cardiac Contractility Modulation (CCM)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
  - The medical necessity of each individual request
  - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
  - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Cardiac contractility modulation (CCM) is a device-based therapy proposed for heart failure (HF) patients with decreased ejection fraction who are not candidates for other treatments, such as cardiac resynchronization therapy. Electrical impulses delivered to the heart muscle are purported to assist the heart in pumping blood more effectively and potentially reduce symptoms such as breathlessness, fatigue, and lower extremity edema.[1,2] A series of 1-3 pulses (4.5–7.5 V) is generated for approximately 5 milliseconds during the absolute refractory period of a cardiac cycle. Stimulation cycles are typically 1 hour in duration, with 7 cycles throughout the day and breaks of 2-3 hours per day.[3,4]

Medical Necessity Criteria

Indications

Cardiac contractility monitoring (CCM) is considered appropriate if **ANY** of the following is **TRUE**:

- This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

Cardiac contractility monitoring (CCM) is not considered appropriate if **ANY** of the following is **TRUE**:

- This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes

0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis,

	including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system
C1824	Generator, cardiac contractility modulation (implantable)
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only

Medical Evidence

Yuecel et al. (2024) compared cardiac contractility monitoring (CCM) and cardiac resynchronization therapy for patients with chronic heart failure (HF). Outcomes at 12-month follow-up were similar; however, hospitalizations occurred more frequently for CCM patients than for those who received cardiac resynchronization therapy. The authors noted that included the timing of the procedures and the correlation with the progression and stage of HF was a limitation.[5]

Pipilas et al. (2023) published a systematic literature review regarding the current and future directions of CCM for HF. At the time of their review, only two devices, the Optimizer Smart and the Optimizer Smart Mini, had received FDA approval. Their review concluded that in both randomized and nonrandomized clinical trials, New York Heart Association (NYHA) Class II-III patients with left ventricular ejection fraction between 25% and 45% most often benefited from CCM therapy. They stated that a positive effect exists with CCM; however, verification and further study in prospective, randomized controlled trials are necessary.[6]

Nadeem et al. (2020) conducted a systematic review and updated meta-analysis of randomized controlled trials regarding all-cause mortality outcomes of the usage of CCM in patients with dilated cardiomyopathy who were ineligible for cardiac resynchronization therapy (CRT). Patients in this group had dilated cardiomyopathy and were divided into a CCM group and a standard therapy group, and were followed for 12 weeks or longer. In their analysis of 930 patients, the CCM therapy group showed no significant reduction in all-cause mortality compared to the standard therapy group. The researchers concluded that there was a need for a large, randomized controlled trial to determine CCM efficacy.[7]

Three randomized controlled trials (RCTs) were conducted on the safety and efficacy of CCM. Abraham et al. (2018) found that CCM was effective for patients with moderate to severe HF however, the study was small (160 patients) and the limited follow-up did not allow for evaluation of long-term effects (e.g., hospitalization, mortality).[8] Kadish et al. (2011) performed a RCT

with 428 patients with advanced HF. While therapy was found to be safe and effective, there was no improvement in the ventilatory anaerobic threshold (VAT).[9] Borggrefe et al. (2008) conducted a randomized, double blind, crossover study of 164 symptomatic patients with HF. Outcomes were positive; however, the authors noted that the short duration of 3 months was a limitation of the study, as CCM therapy could require a longer period of time.[10]

In a 2016 systematic review, Abi-Samra and Gutterman discussed the clinical results of the current literature at that time. FDA-approved pharmacological and device-based treatments for HF with reduced ejection fraction (HFrEF) were stated to be limited, and CCM could fill the gap in current treatment for selected patients. Regarding long-term outcomes, the writers discuss retrospective trial outcomes and acknowledge that at that time, there had been no prospective CCM trials with mortality as a primary outcome. The need for such a prospective randomized trial is emphasized. Special applications and evaluations in CCM use include expansion of the duration of daily CCM stimulus, use in cardiac resynchronization therapy (CRT) failures, HF with preserved ejection fraction, and atrial fibrillation.[11]

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Policy Revision History/Information

Original Date: August 2, 2024		
Review History		
Version 2	08/14/2025	Annual review. Updated the Description to include information about the series of pulses and stimulation cycles. Added HCPCS C1824 and K1030. Expanded the Medical Evidence section; added 4 citations.